

Application No.: 10/822,200
Amendment and Response filed on July 25, 2006
Reply to Office Action of May 25, 2006
Docket No.: 760-129 DIV/CIP/CON II/RCE
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REMARKS

Reconsideration of the application as amended is respectfully requested.

REMARKS/ARGUMENTS:

Status of Claims

Claims 29-49 are pending in the application. Claims 1-28 have previously been cancelled.

Discussion of the Amendments to the Claims

The claims have been amended to point out more particularly and to claim more distinctly the present invention. In particular, claims 31 and 43 have been amended as suggested by the Examiner to change "said first ePTFE tube" to --said first ePTFE tubular structure--. Claim 32 also has been amended as suggested by the Examiner to change "said self-sealing material" to --said self-sealing gel--. Moreover, claims 47-48 have been amended to delete the word "about." Support for the amendments to claims 47-48 may be found in Example 2, particularly at Table 1. No new matter has been added by way of the amendments to the claims.

Discussion of the Rejection under 35 U.S.C. §, First Paragraph

Claims 47-48 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. In particular, the Examiner alleges that there is no support in the specification for the phrases "radial tensile strength of *at least about* 0.48 kg/mm²" and "elongation of *at least about* 690%." (Office Action, page 2).

Applicants respectfully submit that the claim language "radial tensile strength of at least about 0.48 kg/mm²" and the claim language "elongation of at least about 690%" is adequately supported by the subject application. In particular, Example 2 discloses a graft having a tensile

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strength of 0.48 kg/mm^2 and which is capable of withstanding elongation of 690% without breaking. In this regard, Applicants respectfully submit that the subject application need not exemplify radial tensile strengths greater than 0.48 kg/mm^2 or elongation greater than 690% for claims 47 and 48, respectively, as originally submitted or as amended herein, to be adequately supported.

Furthermore, in an effort to advance prosecution and not in acquiescence of the rejection, Applicants have amended claims 47 and 48 to delete the word "about." In view of the amendments to claims 47-48, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

Discussion of the Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 31, 32, and 43 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, the Examiner alleges that there is insufficient antecedent basis for the limitation "said first ePTFE tube" in line 2 of each of claims 31 and 43. (Office Action, page 3). Moreover, the Examiner alleges that there is insufficient antecedent basis for the phrase "said self-sealing material" in line 1 of claim 32. (*Id.*). In response, claims 31 and 43 have been amended to change "said first ePTFE tube" to --said first ePTFE tubular structure-- as suggested by the Examiner. Moreover, claim 32 has been amended to change "said self-sealing material" to --self-sealing gel-- as also suggested by the Examiner.

In view of the amendments to claims 31, 32, and 43, it is respectfully submitted that the basis for the rejection with regard to those claims is moot. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

Discussion of the Rejection Under 35 U.S.C. §102(b) in View of Okita

Claims 29-31, 40-43, and 45-49 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 4,193,138 to Okita. In particular, the Examiner, citing column 3, lines 44-50 and Figure 6, alleges that Okita discloses a multilayer ePTFE graft including a first ePTFE tubular structure having a first internodal distance and a second ePTFE tubular structure having a second internodal distance. Moreover, the Examiner, citing column 7, lines 26-30 and 60-65 and column 8, lines 9-12, alleges that Okita discloses a flowable form, particularly gelled or soluble polymers. The rejection under 35 U.S.C. §102(b) is traversed for the reasons set forth below.

For a cited reference to anticipate a claim under 35 U.S.C. §102(b), that reference must disclose all of the limitations of the claim. Okita, however, fails to disclose a prosthesis including two tubular ePTFE structures as required by all of claims 29-31, 40-43, and 45-49. Rather, Okita at column 3, lines 44-50 and at Figure 6 discloses one tube of ePTFE where the fibrous structure is larger at the outside of the tube than at the inside of that same tube.

Moreover, Okita fails to disclose a self-sealing gel selected from the group consisting of consisting of gelatin, collagen, albumin, casein, algin, carboxymethyl cellulose, carageenan, furcellan, agarose, guar, locus bean gum, gum arabic, hydroxyethyl cellulose, hydroxypropyl cellulose, methyl cellulose, hydroxyalkylmethyl cellulose, pectin, partially deacetylated chitosan, starch and starch derivatives, including amylase and amylopectin, xanthan, polylysine, hyaluronic acid, and its derivatives, heparin, their salts, and mixtures thereof as required by claims 29-31 and 40-43. Indeed, there is no disclosure of any of these specific self-sealing gels at column 7, lines 26-30 and 60-65 and at column 8, lines 9-12.

Furthermore, there is no disclosure in Okita of a biodegradable material interposed between first and second tubular structures as required by claim 45. Accordingly, Okita does not anticipate claims 45-46.

With regard to claims 47-49, the Examiner alleges that Okita uses the same materials and therefore inherently discloses the properties of those claims. Applicants respectfully disagree.

For a reference to anticipate claimed subject matter on the basis of inherency, that reference must necessarily disclose the subject matter which is alleged to be present in the reference. *See* M.P.E.P. §2112. However, it has not been established that the prosthesis of Okita necessarily exhibits a radial tensile strength of at least about 0.48 kg/mm^2 as required by original claim 47 or of at least 0.48 kg/mm^2 as required by claim 47 as amended herein. Likewise, the Examiner has not established that the prosthesis of Okita is capable of withstanding elongation of at least about 690% without breaking as required by original claim 48 or elongation of at least 690% without breaking as required by claim 48 as amended herein. Moreover, the Examiner has not established that the prosthesis of Okita exhibits no or immeasurable leakage subsequent to puncture with a water source as required by claim 49.

Significantly, in view of the many variables attendant manufacture of a multi-layered ePTFE graft, it is not necessarily the case that two grafts made from ePTFE will exhibit the same properties. Indeed, the grafts recited in claims 29-31, 40-43, and 45-49 are quite different from the prosthesis of Okita (for example, the multi-layered grafts recited in claims 29-31, 40-43, and 45-49 include two tubular ePTFE structures while the prosthesis of Okita only includes one ePTFE tube). Moreover, the method of manufacturing the prosthesis of Okita is quite different than the method of manufacturing the present multi-layered grafts. Indeed, there is no disclosure in Okita of manufacturing a multi-layered graft in the manner set forth in Example 2 of the subject application (which graft exhibits the properties recited in claims 47-48), much less an exemplification in Okita of a multi-layered graft having the properties recited in claims 47 and 48 both as originally presented or as amended herein. Likewise, there is no disclosure in Okita of manufacturing a graft that exhibits no or immeasurable leakage 30 seconds subsequent to puncture with a water source as there is in Example 3 of the subject application.

In view of the foregoing, Okita fails to anticipate claims 29-31, 40-43, and 45-49. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(b) in view of Okita.

Discussion of the Rejection Under 35 U.S.C. §102(b) in View of Tu

Claims 47-48 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 4,816,339 to Tu et al. (hereinafter "Tu"). In support of this position, the Examiner alleges the following: "Tu's graft inherently possesses the same properties of elongation and strength claimed, since the same material of the applicant is used, ePTFE having the same internodal distance used by the applicant (col. 2, lines 43-55; col. 5, lines 22-28), sinter temperature (see examples), etc." (Office Action, page 4). Applicants respectfully traverse the rejection under 35 U.S.C. §102(b) in view of Tu for the reasons set forth below.

As noted above, for a reference to anticipate claimed subject matter on the basis of inherency, that reference must necessarily disclose the subject matter which is alleged to be present in the reference. *See* M.P.E.P. §2112. However, the Examiner has failed to establish that the graft of Tu would necessarily possess a radial tensile strength of at least about 0.48 kg/mm², as required by original claim 47, or of at least 0.48 kg/mm², as required by claim 47 as amended herein. Likewise, the Examiner has failed to establish that the graft of Tu would necessarily be capable of withstanding elongation of at least about 690% without breaking, as required by original claim 48, or elongation of at least 690% without breaking, as required by claim 48 as amended herein.

In support of his position, the Examiner alleges that Tu uses PTFE having the same internodal distances used by the Applicant. However, such is not the case. In particular, Tu, at column 2, lines 43-54, and at column 5, lines 22-28, discloses a graft having a luminal layer of PTFE having an internodal distance of about 20 μ to about 30 μ and a second layer having an internodal distance of from about 30 μ to about 500 μ . This is in contrast to the subject application, which discloses a graft having an inner tubular ePTFE layer having an internodal distance of between 40 and 100 μ and an outer tubular ePTFE layer having an internodal distance of about 15 to 35 μ . (See ¶¶ [0039]-[0040]). In this regard, unlike the graft of Tu, the graft in Example 2 of the present invention, which graft exhibits the properties recited in claims 47-48,

has an inner tubular layer having a greater internodal distance than the outer tubular layer. Accordingly, the graft of Tu is quite different from the graft of the present invention and, as such, it is not necessarily the case that the graft of Tu has the same radial tensile strength or is capable of withstanding the same extent of elongation without breaking.

Moreover, none of the examples in Tu disclose the use of a sintering temperature of 660°F as set forth in Example 2 of the present invention. Furthermore, although certain examples in Tu disclose sintering temperatures falling within the range used in the present invention, it does not necessarily follow that the graft of Tu has a radial tensile strength of at least about 0.48 kg/mm², as required by original claim 47, or of at least 0.48 kg/mm², as required by claim 47 as amended herein. Nor does it necessarily follow that the graft of Tu is capable of withstanding elongation of at least about 690% without breaking, as required by original claim 48, or elongation of at least 690% without breaking as required by claim 48 as amended herein. As one of ordinary skill in the art would appreciate, other manufacturing parameters besides sintering temperature will impact the final properties of an ePTFE graft. For example, duration of sintering, the thickness of the ePTFE, and the rate at which ePTFE is expanded will all affect the properties of an ePTFE graft.

Thus, given the numerous manufacturing parameters that may affect the properties of an ePTFE graft and given the distinctions between the graft of the present invention and the graft of Tu, it cannot be summarily concluded that Tu discloses ePTFE grafts as recited in claims 47-48 as originally presented or as amended herein. Indeed, there is no exemplification in Tu of an ePTFE graft having a radial tensile strength of 0.48 kg/mm² or of an ePTFE graft that is capable of withstanding elongation of 690% without breaking as there is in the subject application.

In view of the foregoing, Tu does not expressly or inherently disclose a graft as recited in claim 47 (as originally presented or as amended herein) or a graft as recited in claim 48 (as originally presented or as amended herein). Accordingly, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §102(b) in view of Tu.

Discussion of the Rejection Under 35 U.S.C. §103(a)

Claims 29-34, 37-46, and 49 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,383,214 to Banas et al. (hereinafter "Banas") in view of U.S. Patent No. 6,391,052 to Buirge et al. (hereinafter "Buirge"). In particular, the Examiner alleges that Banas discloses an adhesive sealing material interposed between two tubular grafts having different internodal distances. Although the Examiner acknowledges that Banas does not disclose the particular self-sealing gels recited in the claims, the Examiner nevertheless contends that it would have been obvious to one having ordinary skill in the art to use the collagen gel of Buirge to bond two tubular grafts together. The rejection under 35 U.S.C. §103(a) is respectfully traversed for the reasons set forth below.

To establish a *prima facie* case of obviousness, the Examiner must establish that the cited combination of references disclose, teach or suggest every limitation of the claimed invention. Moreover, the Examiner must establish not only that there is some motivation to combine the teachings of the cited references, but also that there is a reasonable expectation of achieving the claimed invention upon doing so. *See* M.P.E.P. § 2142. The Examiner has failed to make this requisite showing.

Banas is directed to a stent-graft having a stent encapsulated between two ePTFE coverings. (See, e.g., abstract). Although Banas discloses the use of an adhesive to bond the ePTFE tubular layers, there is no disclosure, teaching or suggestion of interposing the specific self-sealing gels recited in independent claims 29 and 41 between two ePTFE grafts as required by those claims. Accordingly, it cannot properly be said that Banas discloses, teaches or suggest a multi-layered graft as required by claims 29-34 and 37-44. Moreover, there is no disclosure, teaching or suggestion in Banas of a multi-layered ePTFE vascular graft including a biodegradable material interposed between two first and second ePTFE tubular structures as required by claims 45-46. Nor is there a disclosure, teaching or suggestion of a graft having a self-sealing material interposed between first and second ePTFE tubular structures, wherein the

graft exhibits no or immeasurable leakage 30 seconds subsequent to puncture with a water source as required by claim 49.

Turning to Buirge, that reference does not overcome the deficiencies of Banas. Buirge is directed to a method of depositing collagen coatings on a metal surface. Although Buirge discloses the use of a collagen gel as an adhesive to join a stent to a collagen sleeve, there is no disclosure, teaching or suggestion of interposing a self-sealing gel between two ePTFE tubular structures as required by all of claims 29-34 and 37-44. Moreover, Buirge, like Banas, fails to disclose, teach or suggest a biodegradable material interposed between first and second tubular structures as required by claims 45 and 46. Additionally, as there is no disclosure, teaching or suggestion in Buirge of a graft having a self-sealing material interposed between first and second ePTFE tubular structures wherein the graft exhibits no or immeasurable leakage 30 seconds subsequent to puncture with a water source, Buirge also fails to render claim 49 obvious.

Furthermore, one of ordinary skill in the art would not even be motivated to combine the disclosures of Banas and Buirge. As noted above, Banas is directed to stent-grafts that include ePTFE. Buirge, on the other hand, specifically teaches away from the use of ePTFE, stating that the biological and physical advantages of the invention disclosed in Buirge cannot be provided by synthetic sleeves such as PTFE (see column 6, lines 31-33, of Buirge).

In view of the foregoing, claims 29-34, 37-46, and 49 are not obvious in view of the combination of Banas and Buirge. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103(a).

Remarks Regarding Allowable Subject Matter

Applicants appreciate the indication that claims 32 and 34-39 would be allowable if claims 32 and 35-36 were rewritten as proposed by the Examiner. However, in view of the arguments submitted herein, it is respectfully submitted that claims 32 and 35-36 are allowable in their present form.

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Moreover, with regard to claim 32, Applicants note that the self-sealing material of claim 32 (as originally presented) and the self-sealing gel of claim 32 (as amended herein) are distinct from the two tubular ePTFE structures. Therefore, it is respectfully submitted that it would be understood that the self-sealing material of claim 32 (as originally presented) and the self-sealing gel of claim 32 (as amended herein) may include a thermoplastic elastomer and/or fluoropolymer which is/are distinct from the ePTFE tubular structures recited therein without amendment to claim 32 as proposed by the Examiner.

Concluding Remarks

The claims are believed to be allowable over the art and the application in good and proper form for allowance. The Examiner is invited to contact the undersigned if she has any questions regarding this submission or, if in her opinion, a teleconference call would expedite prosecution of the subject application.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R. § 1.17, and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

Respectfully submitted,


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